

APPLICANT(S): Michael GOLDBERG et al.

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## **REMARKS**

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

### **Status of Claims**

Claims 1-22, 24, 25, 27-29, 33-38 and 40-67 are pending and are under examination in this application, and have been rejected in the final Office Action dated February 8, 2008.

Applicants have herein amended claims 1, 16, 24, 25, 29, 33, 34, 46, 47, 48, 65 and 67 and have canceled claims 46 and 66. It is submitted that these amendments add no new matter.

Applicants thank the Examiner for the courtesies extended during the telephone interview on Thursday, February 14, wherein the Examiner and the undersigned attorney for Applicants discussed the claim rejections and claim amendments that would overcome the pending rejections.

### **Claim Objections**

In the final Office Action, the Examiner objected to Claims 1, 16, 34 and 66 for reciting “a pharmaceutically acceptable delivery agent 4-CNAB”, wherein all but “4-CNAB” is superfluous and grammatically incorrect. Applicants have corrected the claims so that they more properly refer to “the delivery agent 4-CNAB”.

### **35 U.S.C. § 112 Rejections**

In the final Office Action, the Examiner rejected Claim 29 under 35 U.S.C. § 112, first paragraph, as not complying with the enablement requirement. According to the Examiner, claim 29 recites “prophylactically reducing beta cell function”, and Applicants have not enabled the term “prophylactically”. In response, and in order to expedite prosecution, Applicants have amended claim 29 to recite “reducing beta cell function”.

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The Examiner also rejected Claims 24, 48, 66 and 67 under 35 U.S.C. § 112, first paragraph, as not complying with the written description requirement. According to the Examiner, these claims recite that the delivery agent “comprises” 4-CNAB, and the specification teaches that the delivery agent is 4-CNAB. In response, and in order to expedite prosecution, Applicants have amended claims 24, 48 and 67 (claim 66 has been canceled) so that these claims recite “wherein said 4-CNAB comprises about 300 mg 4-CNAB” to clarify that only the amount of 4-CNAB is being modified in these dependent claims.

The Examiner further rejected Claims 1-22, 24, 25, 27-29, 33-38 and 40-67 under 35 U.S.C. § 112, first paragraph, as being indefinite. The Examiner seems to believe that the language used in claim 1 renders the language of these dependent claims redundant, not grammatically proper and not properly subgeneric to independent claim 1. In response, and in order to expedite prosecution, Applicants refer to the amendments to claims 1, 16, 24, 25, 29, 33, 34, 46, 47, 48, 65 and 67, which Applicants believe solve the issues noted by the Examiner.

Applicants respectfully request that the Examiner withdraw these rejections.

### **35 U.S.C. § 103 Rejections**

In the Office Action, the Examiner rejected Claims 46 and 65 under 35 U.S.C. § 103 as being unpatentable over:

- (a) Pilarski (U.S. Patent No. 7,137,951) in view of Byrd (U.S. Patent No. 7,118,762) or Moye Sherman (U.S. Patent No. 7,115,663) or Ekwuribe (U.S. Patent No. 7,084,114) or Ekwuribe (U.S. Patent No. 7,060,675).
- (b) Ekwuribe (U.S. Patent No. 7,060,675).
- (c) Miller et al. (Clinical Pharmacology and Therapeutics 53(3), 380-4, 1993) in view of Mesiha et al. (International Journal of Pharmaceutics 249(1-2), 1-5, 2002), Hosny et al. (International Journal of Pharmaceutics 237(1-2), 71-6, 2002), or Clement et al. (Diabetes Technology & Therapeutics 4(4), 459-66, 2002).
- (d) Yki-Jarvinen et al. (Annals of Internal Medicine 130(5), 389-96, 1999) in view of Mesiha et al., Hosny et al., or Clement et al.

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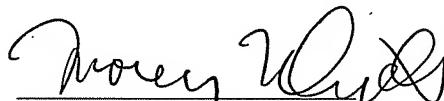
Applicants traverse these rejections. Applicants note that amended independent claims 25 and 34 were not rejected under 35 U.S.C. § 103 and are allowable. Applicants also note that dependent claims 46 and 65 depend from amended independent claims 25 and 34, respectively, such that claims 46 and 65 should also not be rejected by virtue of their dependence on those amended independent claims 25 and 34. Applicants respectfully request that claims 46 and 65 be passed to allowance.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: February 20, 2008

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